AD_____

GRANT NUMBER DAMD17-96-1-6270

TITLE: Breast Cancer and Risk Factors Among African-American Women Aged 20-54: A Case-Control Study According to Estrogen Receptor

PRINCIPAL INVESTIGATOR: Kangmin Zhu, Ph.D.

CONTRACTING ORGANIZATION: Meharry Medical College
Nashville, TN 37208

REPORT DATE: September 1997

TYPE OF REPORT: Annual

PREPARED FOR: Commander
U.S. Army Medical Research and Materiel Command
Fort Detrick, Frederick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release;
distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

19980116 164

DTIC QUALITY INSPECTED 3

# REPORT DOCUMENTATION PAGE

*Form Approved*
*OMB No. 0704-0188*

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503.

| 1. AGENCY USE ONLY *(Leave blank)* | 2. REPORT DATE | 3. REPORT TYPE AND DATES COVERED |
|---|---|---|
| | September 1997 | Annual (1 Sep 96 - 31 Aug 97) |

**4. TITLE AND SUBTITLE**
Breast Cancer and Risk Factors Among African-American Women Aged 20-54: A Case-Control Study According to Estrogen Receptor

**5. FUNDING NUMBERS**
DAMD17-96-1-6270

**6. AUTHOR(S)**
Kangmin Zhu, Ph.D.

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**
Meharry Medical College
Nashville, TN 37208

**8. PERFORMING ORGANIZATION REPORT NUMBER**

**9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)**
Commander
U.S. Army Medical Research and Materiel Command
Fort Detrick, Frederick, Maryland 21702-5012

**10. SPONSORING/MONITORING AGENCY REPORT NUMBER**

**11. SUPPLEMENTARY NOTES**

**12a. DISTRIBUTION / AVAILABILITY STATEMENT**
Approved for public release; distribution unlimited

**12b. DISTRIBUTION CODE**

**13. ABSTRACT** *(Maximum 200*

This is an exploratory case-control study that aims to examine whether risk factor profiles differ according to estrogen receptor (ER) status among African-American women. Since the initiation of the study in September 1997, tremendous efforts have been made to formulate the study procedures, contact doctors, identify and recruit study subjects, and make various preparations. During several months from the research assistants' joining the team to August 31, the research team has repeatedly contacted 79 doctors to get their consent for contacting their patients (the first wave of patients we obtained from the Tennessee Cancer Reporting System). Fifty-five doctors responded to our study, with 108 patients available to contact. Among these patients, 39 agreed to participate in the study and a telephone interview has been conducted with 33 of them as of August 31. Although our research team has made great efforts to recruit more patients, the response rates of doctors and patients have been lower than we expected. Therefore, we recommend including eligible patients diagnosed not only in 1995-96, but also in 1997 to increase the number of cases. Random-digit telephone dialing procedures for selecting controls have been started and will be evaluated.

**14. SUBJECT TERMS** Breast Cancer
African-American women, breast cancer, case-control study, epidemiology, estrogen-receptor, risk factors

**15. NUMBER OF PAGES**
89

**16. PRICE CODE**

| 17. SECURITY CLASSIFICATION OF REPORT | 18. SECURITY CLASSIFICATION OF THIS PAGE | 19. SECURITY CLASSIFICATION OF ABSTRACT | 20. LIMITATION OF ABSTRACT |
|---|---|---|---|
| Unclassified | Unclassified | Unclassified | Unlimited |

## FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

____ Where copyrighted material is quoted, permission has been obtained to use such material.

____ Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

____ Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

____ In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

__✓__ For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

____ In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

____ In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

____ In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

[signature] 9/16/97

PI - Signature Date

**TABLE OF CONTENTS**


01. Cover page .....1

02. SF 298 .....2

03. Foreword .....3

04. Table of content .....4

05. Introduction .....5-6

06. Body .....6-18

07. Conclusions .....18-19

08. References .....20

09. Appendices .....21-89

## INTRODUCTION

This is an annual report regarding our case-control study that aims to examine whether risk factor profiles of breast cancer differ according to the estrogen receptor (ER) status among African-American women ages 20-64. This report covers the period from September, 1996 to August 31, 1997.

It was the first year of this exploratory study. Therefore, tremendous efforts had to be made to set up the study procedures, to make various preparations, to recruit study subjects and to initiate interviews. The award notification from the Department of Grants and Contracts Administration, Meharry Medical College, was given to the principal investigator on September 16, 1996. Upon the receipt of the award notification, the principal investigator, Dr. Zhu, began a series of preparations for the study, such as developing the quality control related procedures, polishing the questionnaire, working on the IRB and budget related issues and hiring research team members. Due to the position-control and employment process and procedures of the Meharry and the selection process, the research specialist (research coordinator) and the research assistants were able to be on board in February, April and May, 1997, respectively. The Research Specialist, Ms. Sandra Hunter has done a lot of coordination and other needed work for the project since she joined the team in February. She performed pre-interviews with selected women to test the questionnaire and gain their feedback and comments. She also handled miscellaneous affairs for the study, including ordering supplies, contacting study field coordinator, contacting doctors and study women, working on various forms and documents needed for the study and helping with hiring research assistants. The research assistants, Ms. Kathleen Payne-Wilks and Ms. Chanel

Roland, joined the preparation process. They received training on the interview skills, knowledge of breast health and study quality control. During the study, they have made great efforts to contact doctors and study subjects and to schedule and conduct interviews.

The project had been going for less than 12 months up to August 31, with the interviewers employed in April and May. During the period, the project has progressed. The research team has done a lot of preliminary work and has done their utmost to increase the participation of doctors and eligible women. Since interviews started only a few months ago, we currently do not have the questionnaire-based results available for this report. The following is the summary of the work done up to August 31, 1997.

## BODY

### 1. Study Hypothesis

Estrogen-related factors, such as nulliparity, age at first full-term pregnancy, age at menarche, and age at menopause, are known to be risk factors for breast cancer [1]. Because estrogen executes its influence on the biological activity and growth rate of breast cells through hormone receptors [2], whether these factors can increase the risk of breast cancer may depend upon the existence of estrogen receptors. Therefore, it is reasonable to hypothesize that risk factor profiles may differ according to estrogen receptor (ER) status of tumor.

## 2. Study Design

This study uses a case-control design to examine whether risk factor profiles are different between ER-positive and ER-negative tumors among African-American women. Cases consist of about 200 African-American female patients diagnosed with breast cancer during 1995-96 and who lived in Davidson, Shelby and Hamilton counties, Tennessee. All breast cancer patients were histologically confirmed (ICD-O site code C50) [3] and identified through Tennessee Cancer Reporting System (TCRS). Controls are comprised of African-American women without breast cancer who are selected through random-digit telephone dialing and frequency matched to cases by 5-year age range. Information on risk factors is collected through telephone interviews. Tumor tissue samples are collected and pathological reports are reviewed (when necessary) for the determination of estrogen receptor status. In addition, a set of colored pictures of oral contraceptive (OC) pills and a short OC questionnaire are mailed to the study subjects with the pay check to collect detailed information about OC use.

## 3. Methods And Procedures Implemented

Figure 1 shows the study procedures, which include identifying and selecting cases and controls, getting consent from doctors and eligible women, performing interviews, collecting tumor tissues and reviewing pathological reports when needed. For a high study quality, we need to train interviewers and conduct quality-control procedures.

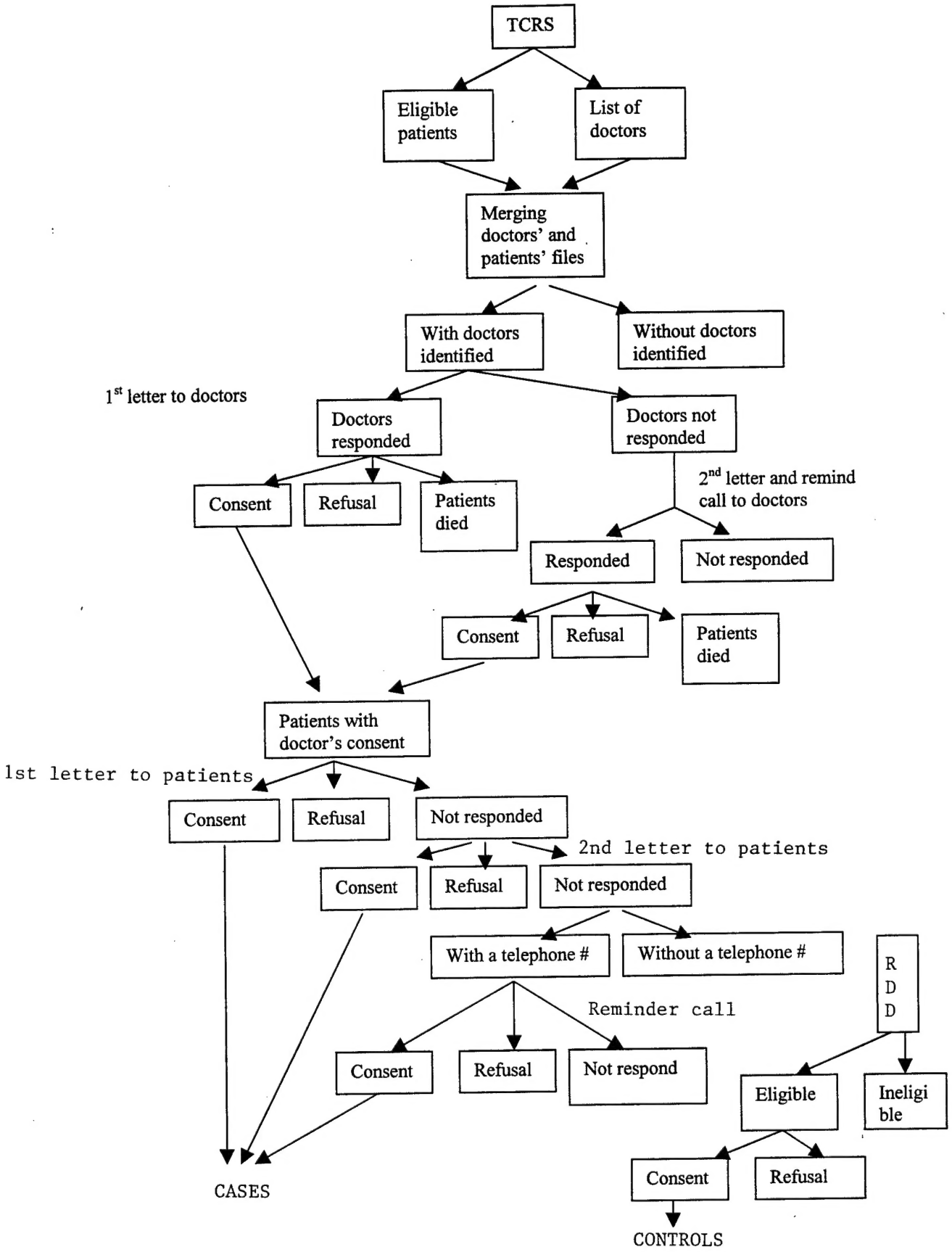



Figure 1. Procedures for getting consent from doctors and patients

3.1. Identification of study women

Cases with breast cancer are selected through TCRS. TCRS was established in 1986 and requires hospitals and certain laboratories to report cancer patients within 6 months of their diagnosis. Ms. Becky Jones and Mr. Patrick Turri are TCRS collaborators for the study. Before the start of the study, our research team members had a meeting with TCRS collaborators to discuss the criteria for the eligibility of study subjects and detailed procedures to recruit them. Ms. Jones and Mr. Turri provide us with a list of patients according to the selection criteria on a quarterly basis. They also provide us with a list of all doctors in Tennessee. We match patients with their doctors and send a letter to the doctors for their consent to contact their patients. Patients with a doctor's consent are sent a cover letter introducing the study and a consent form for their participation in the study (appendix 1). The second letter is sent to those who did not respond to the first one. A reminder call (where a telephone is available) is made to women who did not reply to both mailings. Only patients who completed a consent form are used as cases for the study.

Controls are selected using random digit dialing techniques, and frequency matched to cases by 5-year age range. The first step of control selection by random digit dialing (RDD) is to group cases diagnosed in the same calendar year whose telephone area codes and prefixes serve the same residence area, and then form the sampling frame by age distribution of the cases in the area. By randomly selecting one of the telephone prefixes of the cases and adding the last four random-selected digits, a call is made to find an eligible woman according to ethnic background and age range.

For each telephone number called, interviewers determine (1) whether it is a residential or nonresidential (business line, cellular network, fax machine, disconnected, or changed to another number,) number; (2) whether there are any eligible women for a residential number; (3) how many eligible women there are (randomly select one using the last two digits of the telephone number, if more than one eligible women); and (4) whether an eligible woman consents to have an interview. Up to 9 calls over a two week period, including 3 day-time, 3 evening, and 3 weekend calls, are made for a telephone number that has not answered. If an eligible woman is identified, we describe the study purposes and procedures, and ask whether she would accept a telephone interview. For a woman who agrees to participate, a telephone interview is conducted.

To achieve a high response rate, we use a monetary incentive. We mention to eligible women that we will pay them for their time for the study ($25 for a completed interview) and also provide them an opportunity to be entered in a drawing for an award of $200.

3.2. Identification of doctors and doctors' consent

TCRS provides us the names and addresses of eligible patients' physicians. We mail the doctors a letter (appendix 2) and a consent form (appendix 3). The letter we send describes the study and asks if we can contact their patients. If a physician does not return the consent form after two mails, one of our staff members calls the physician's office to determine the status of the letter and fax or mail another copy of the letter and consent form

when needed. We recognize that continuing support from doctors is very important for us to recruit patients. To establish a good relationship with doctors, Dr. Zhu writes a thank you card to each doctor who responded to our study.

### 3.3. Test and revision of questionnaires

Ms. Hunter performed pre-interview test with five African-American women to gain feedback concerning the questionnaire. These women represented the various backgrounds including breast cancer patient, nurse, house wife, engineer and customer service representative. All the participants agreed that the questions are suitable and the women would feel comfortable with the questionnaire. However, they recommended changing the order of the questions for further improvement. They suggested that the questionnaire begin with less sensitive questions (i.e. background, personal habit and lifestyle) and put more direct questions (i.e. medical history) later. Based upon the comments from the pre-interview test, revisions were made to the questionnaire. This helped the subjects feel more at ease with the interview process (appendix 4).

### 3.4. Training of interviewers

Telephone interviewers were trained on conversation skills on the telephone, general knowledge of breast cancer, and ways to address the concerns a subject may have. They were also trained to improve their performance in reducing under-reporting of information and item non-response, avoiding inductive questioning and evading inferring from an incomplete or

inadequate reply. They were asked to examine completed questionnaires immediately after an interview for any errors, inconsistencies, unusual answers and missing values, and to make corrections or compensations where possible. An overview of interview procedures (appendix 5) and a brief interview guide (appendix 6) were provided to the interviewers

3.5. Data collection

We use telephone interview technique for the information on breast cancer risk factors. Measurement of tumor tissues and medical record review (when needed) will be used for the determination of ER status. Because study women may not be able to recall the use of oral contraceptive pills accurately, we send them a set of colored OC pill pictures and a short form (appendix 7) with a paycheck after the telephone interview. The women are asked to complete the OC form and return it to us using the enclosed stamped envelope.

3.6. Quality control-related work and procedures

A. Evaluating interviews: For the fidelity of interviews, Ms. Sandra Hunter, the supervisor of interviewers, randomly chooses 20% of interviewed women and asks them over the phone six selected questions to make sure that an interview has been made, the questions have been answered and the answers have been accurately recorded.

B. Monitoring and improving RDD calls: All telephone calls and their outcomes are

recorded. Therefore, we can monitor every component of the response rate for RDD, including the number of answering machines, busy line, ineligible women, etc. This information allows us to know the changes over time in non-response and modify maneuvers to improve response.

C. Data editing: A three-step edit process (interview edit, editor edit, and coder edit) is taken. During editing, a completed form is examined for any errors, inconsistencies, unusual answers and missing values. Corrections or compensations by such as calling back to the subject are made when necessary. After data are entered in the computer, another examination is conducted to correct any errors in entering data.

D. Research administration: In addition to day-to-day communications on the research activities, we established a weekly-meeting system. In the meeting, the progress of the past week is summarized. All research members are asked to present and discuss any potential problems and good experiences in communications with study women. To reduce any possible errors in document and data handling, we developed a flowchart for data handling procedures (appendix 8). Mrs. Sandra Hunter arranges all data collection activities and examines and maintains all data to avoid or reduce any overlapping, missing or inaccuracy. In addition, a subject tracking system (appendix 9) was developed to integrate data from the different sources.

## 4. Current Status Of Study

### 4.1. Doctors' consent

As the first wave of data, TCRS provided us 187 eligible patients with breast cancer. Out of the patients, 22 had no doctors identified. The common reasons for no doctors identified are that only a resident or hospital rather than a doctor was indicated, or doctor was in rotation. A packet containing a cover letter and a consent form was sent to 79 identified doctors. For doctors who did not respond, we sent the second packet and made a reminder call if they did not respond to the second mail either. A doctor we contacted kindly provided consent for the additional African-American patients she diagnosed in recent three years (n=20)(these patients were included as eligible women and duplicates will be excluded if reported to us again by TRCS in the future). Table 1 summarizes doctors' responses to our letters and remind calls.

Overall, 70% of doctors (n=55) responded to our study with the number of 128 patients (69.2% of all patients with a doctor identified). For these patients, doctor's consent was obtained for 108 of them (84.4%).

Table 1. Doctors' responses according to the first mailing, second mailing and reminder call

| | Doctor not responded | Doctor responded | Status of patients with doctor's response | | |
|---|---|---|---|---|---|
| | | | Agreed to contact | Refused to contact | Patient died |
| 1st mail | 54* | 25* | 54** | 8** | 5** |
| 2nd Mail | 41 | 13 | 26 | 0 | 2 |
| Reminder call | 24 | 17 | 28 | 5 | 1 |

*, number of doctors; **, number of patients

4.2. Participation of eligible patients and interviews completed

One hundred and eight patients had doctor's consent for us to contact them. We sent the patients a packet including a cover letter and a consent form. A second packet was sent and a reminder call was made (when a phone number is available and there was no response to the second mailing) for women who did not respond. Table 2 shows the outcomes of our first and second mailings and reminder calls.

Table 2. Patients' responses according to the first mail, second mail and reminder call

| | Women responded | | Women not responded | | Total |
|---|---|---|---|---|---|
| | Agreed to participate | Refused to participate | Unable to locate | Other | |
| 1st mail | 14 | 1 | 4 | 89 | 108 |
| 2nd Mail | 17 | 0 | 2 | 74 | 93 |
| Reminder call | 8 | 8 | 7 | 17 | 40* |

*, the number of patients with a telephone number available.

Among patients to whom we contacted, the percentages of women who agreed and refused to participate in the study were 36.1 and 8.3, respectively. The rest of them either did not respond to the study or could not be located. Up to August 31, thirty-three patients have been interviewed and therefore included in the case group. We subsequently mailed to these cases a set of colored pictures of oral contraceptive (OC) pills and a short OC questionnaire with the paycheck. The completed OC questionnaires are being returned to us.

It is known that African-Americans are less likely to participate in clinical trials or other studies [4,5]. Although we paid participants for their time for the study and provided them with an opportunity to win another $200 and although we have used an intensive

procedures to get their responses, the current participation rate of eligible women is still lower than we expected.

### 4.3. Selection of controls

Random-digit dialing (RDD) for selecting controls was initiated about one week before the end of this report period. Information about the procedure will be available in the next report.

## 5. Recommendations In Relation To The Statement Of Work

### 5.1. Determination of ER status

Before data collection began, our other project had been recommended for funding by the Department of Army. This new project will include the patients of this study and collect tumor tissue specimens for the measurement of ER gene methylation status. Because of the availability of tumor tissues, we suggested to determine ER status using laboratory tests instead of medical record reviews where possible. The reasons for doing so are twofold: (1) ER measurement values based on the same laboratory criteria are more comparable than those from medical records that come from different laboratories; and (2) the laboratory results can be compared with the measurements of ER gene from the same tumor tissues. The comparisons may provide very important information for future studies. The Meharry IRB has approved this change.

5.2. Number of subjects

Although our project staff has made tremendous effort to get a high participation rate of eligible women, the current responses from them are below what we hoped. To get a sufficient number of study subjects, therefore, we may need to have a greater pool of patients. We may add patients diagnosed in 1997.

5.3. Timelines

According to the Statement of Work, the time span for data collection should be from the $7^{th}$ month to the $15^{th}$ month. Because the research assistants for the project were able to be on board only 3 and 4 months ago, the activities for the selection of subjects and collection of data started later than expected. Therefore, we have to extend our time for the activities. The additional reasons for such an extension are (1) a large number of telephone calls (including RDD) and large amount of preliminary work vs. the limited budget, (2) more effort than expected to get doctors' and patients' consent, (3) a proposed expansion of the patient pool, and (4) proposed laboratory measurements of ER status.

CONCLUSIONS

It was the first year of this exploratory case-control study. The research team members have made tremendous efforts to establish the study field, to identify and select

study subjects, and to make various preparations. During several months from the interviewers' joining the team to August 31, we have contacted 79 doctors and interviewed with 33 patients who had a doctor's consent for us to contact and who agreed to participate in the study. A set of colored pictures of oral contraceptive (OC) pills and a short OC questionnaire have been mailed to these study subjects with the paycheck to collect detailed information about OC use. Random-digit telephone dialing procedures for selecting controls have been started.

Seventy percent of doctors we contacted responded to our study and 36% of patients with a doctor's consent agreed to participate. These rates are lower than we expected. Therefore, we propose adding patients diagnosed in 1997 to have more cases. We also will compare the demographic and disease characteristics between responding and non-responding patients to assess the potential effects of the non-responses, using the information from TCRS.

Although our project staff has made tremendous effort, we were unable to finish sufficient interviews in terms of the Statement of Work because of the late employment of the interviewers and the difficulties in getting consent from doctors and patients. In the coming year, we will increase our patient pool to obtain an adequate number of cases. We will conduct RDD to select controls and start collecting information on ER status. We hope that we can get needed information with an extended period for data collection and through our collective effort and diligence.

## REFERENCES

1. Bernstein L, Ross RK. Endogenous hormones and breast cancer risk. Epidemiol Rev 1993;15:48-65.

2. Rayter Z. Steroid receptors in breast cancer. Br J Surg 1991;78:528-35.

3. Percy C, Holten VV, Muir C. International Classification of Diseases for Oncology (2nd edition). Geneva: World Health Organization, 1990.

4. Gorelick PB, Richardson D, Hudson E, Perry C, et al. Establishing a community network for recruitment of African Americans into a clinical trial. The African-American antiplatelet stroke Prevention Study (AAASPS) experience. J Natl Med Assoc 1996 88;701-4.

5. Harris Y, Gorelick PB, Samuels P, Bempong I. Why African Americans may not be participating in clinical trials. J Natl Med Assoc 1996; 88:630-4.

## APPENDICES

1. Letter to study subjects
2. Letter to doctors
3. Consent form for doctors
4. Questionnaire
5. Overview of interview procedures
6. Interview guidelines
7. OC charts and OC form
8. Flowchart for tracking system
9. Flowchart for data handling procedures

MEHARRY MEDICAL COLLEGE

SCHOOL OF MEDICINE

1005 D. B. TODD, JR., BOULEVARD

NASHVILLE, TENNESSEE 37208

(615) 327-6572

DEPARTMENT OF
FAMILY AND PREVENTIVE
MEDICINE

{Date}

{First, Last}
{Address}
{City, ST, Zip Code}

We are requesting your help for an important study on women's health. The purpose of this study is to evaluate African-American women's health status and related events. Your doctor, {First Last, MD,} has given us permission to contact you for the study.

This study involves a 55-70 minute telephone interview, using a specimen of your tumor tissues stored in your hospital, and reviewing your pathological reports when needed. We realize that your time is important, so we'll pay you **$35** for the study. In addition, we will enter your name into a drawing for **$200.**

**By spending only 55-70 minutes for participating in the study, You will receive...**

**$35 and**
**A chance to win $200**

Your participation in the study is completely voluntary. You can skip any questions and stop the interview any time. Whether or not you choose to participate will have no effects on any future health care from any institution or any other benefits to which you are entitled. All information collected will be kept strictly confidential as required by law. Your name will not appear on any reports that may result from this study. To participate, please sign the enclosed consent forms and the release of information form. Please return to us all copies of the signed forms using the enclosed postage-paid envelope. We will mail a copy of the consent forms back to you for your file. Also, please remember to include your telephone number on the consent forms.

We hope you are willing to take part in this important study and help us in improving African-American women's health. If you have any questions, please call Ms. Sandra Hunter, Research Specialist, at (615) 327-6890 between 7:30 a.m. and 4:30 p.m., Monday through Friday. Thank you very much for your time and consideration.

Sincerely,

Kangmin Zhu, M.D., Ph. D.
Principal Investigator

MEHARRY MEDICAL COLLEGE

SCHOOL OF MEDICINE

1005 D. B. TODD, JR., BOULEVARD

NASHVILLE, TENNESSEE 37208

(615) 327-6572

DEPARTMENT OF
FAMILY AND PREVENTIVE
MEDICINE

Date

«FirstName»«middle_initials» «LastName»«End_title_initials», M.D.
«Address1»
«Address2»
«City», «State» «PostalCode»

Dear Dr. «LastName»:

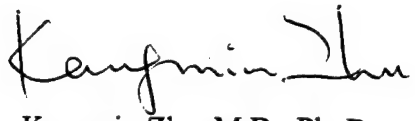
I am writing to you to seek your help for our case-control study on Breast Cancer and Risk Factors among African-American Women. This study is funded by the Department of Defense. As you are aware, African-American women have a higher mortality rate and are more likely to develop estrogen receptor-negative tumors that have worse prognosis. This study aims to evaluate whether etiologic profiles are different according to estrogen receptor (ER) status or methylation status of the ER gene of the disease among African-American women. The results of this study will eventually contribute to the prevention of breast cancer.

The study involves a 55-70 minute telephone interview with patients who have been diagnosed with breast cancer. The patients are identified through the Tennessee Cancer Reporting System. Before the study, we will seek the patient's consent in writing to participate in the study. We will have a telephone interview with the woman who agrees to participate in the study. We will also collect her tumor tissue specimen obtained from the routine diagnostic or treatment procedure, and review her pathological reports when needed. The patient's participation is completely voluntary. The patients will be informed about their rights as a study subject and they can skip any questions or stop the interview any time. We will be paying the participants $35.00 for their time for the study.

This study has been approved by the Meharry Medical College Institutional Review Board. Your patient(s) listed are eligible for the study. We would like your permission to contact the patient(s) for this study. Please indicate on the enclosed consent form the patients whom we can contact, sign the form, and mail it back to our office using the enclosed stamped envelope.

Your support for the study is very important since the validity of the study depends on high participation of eligible patients. We hope that you will be able to assist us in this important research effort. If you have any additional questions concerning the study, please contact Ms. Sandra Hunter at (615) 327-6890. Thank you very much for your time and consideration.

Sincerely,



Kangmin Zhu, M.D., Ph. D.
Principal Investigator

Return To:

Meharry Medical College
Department of Family & Preventive Medicine
Attn: Sandra Hunter, Research Specialist
1005 Dr. D.B. Todd Blvd
Nashville, TN 37208-3599

I give my permission to the research staff of Meharry Medical College to contact the patients for the study whose names I have checked. I have also indicated the patients who are deceased and health status is not suitable for your staff to contact. I understand that any information obtained will be held strictly confidential as required by law.

| **Patient Name** | **Contact** | **Do Not Contact** | **Deceased** | **Phone# (Desirable)** |
|---|---|---|---|---|
| _____ | ___ | ___ | ___ | _____ |
| _____ | ___ | ___ | ___ | _____ |
| _____ | ___ | ___ | ___ | _____ |
| _____ | ___ | ___ | ___ | _____ |
| _____ | ___ | ___ | ___ | _____ |

**Print Name**_____ **Signature**_____ **Date**_____

___ ___ ___

| | |
|---|---|
| **Study ID:** | _____-_____-_____ |
| **Interviewer ID:** | ___ ____ |
| **TCRS#** | ___ ___ ___ ___ |
| **Date of Interview:** | _____/____/____ (month/day/year) |
| **Time Interview Begin:** | ____:____ a.m./p.m. |
| **Time Interview Ended:** | ____:____ a.m./p.m. |
| **Reference Date:** | ____/____ (month/year) |

# WOMEN'S HEALTH STUDY

## (CCS-1)

---

## Meharry Medical College
## Family & Preventive Medicine

**ON THE TELEPHONE:**

Hello, my name is (YOUR NAME). I am from Meharry Medical College. I am calling Ms. _____ (NAME OF SUBJECT).

**IF THE SUBJECT IS HOME:**

How are you, Ms._____ (NAME OF SUBJECT)? I am (YOUR NAME) from Meharry Medical College. As you have agreed, we would like to interview you for our study on Women's Health. Is this a time convenient for you?

No-SAY, What time is good for you? WRITE DOWN: Time_____ Date_____.
SAY, I will call you at that time. Thank you, bye-bye.
Yes- GO AHEAD WITH THE INTERVIEW

**INTRODUCE THE STUDY AND THE SUBJECT'S RIGHTS AGAIN, AND ARRANGE PRIVATE SETTING FOR INTERVIEW.**

**TO BEGIN THE INTERVIEW:**

Now, Ms. (NAME OF RESPONDENT), I would like to begin asking you questions related to the study. I'd like to repeat that your information will be kept completely confidential as required by law, and you also may refuse to answer any questions.

## SECTION A: BACKGROUND INFORMATION

First, I would like to ask some questions about your background.

A1. What is your date of birth? __ __/__ __/__ __
(month, day, year)

A2. Have you ever been married or lived as married?

No (GO TO A5) .....0
Yes .....1

A3. How old were you when you first married or began living as married? __ __ (age)

A4. How many years have you been married and/or living as married? __ __ (years)

A5. What was your marital status when your breast cancer was diagnosed?

Married .....1
Separated .....2
Divorced .....3
Widowed .....4
Never married .....5

A6. Were you employed when your breast cancer was diagnosed?

No .....0
Yes .....1

A7. What was the name of the company and your job title where you worked for the longest period before your breast cancer was diagnosed?

_____ (industry)

_____ (job title) ___ (code)

A8. What was your approximate weight when you were 18 years old? Please exclude weight during pregnancy.

___ (pound)

A9. What was your approximate weight one or two years before your breast cancer was diagnosed? Please exclude weight during pregnancy.

___ (pound)

A10. What is your maximum adult height?

__/__ __
(feet, inches)

A11. What is the highest level of school that you completed before your breast cancer was diagnosed?

No school .....0
Elementary school .....1
Middle school .....2
High school .....3
Vocational or technical training school.....4
Some college or junior college .....5
College .....6
Graduate or professional school .....7
Other (specify) _____.....8

## SECTION B: PERSONAL HABITS AND LIFESTYLE

B1. Did you ever smoke a total of 100 cigarettes or more before your breast cancer was diagnosed?

No (GO TO B9) .....0
Yes .....1

B2. At what age did you start smoking? __ __ (age)

B3. Did you smoke when your breast cancer was diagnosed?

No .....0
Yes (GO TO B5) .....1

B4. How old were you when you quit smoking? __ __ (age)

B5. How many total years did you smoke before your breast cancer was diagnosed? Please exclude any years that you quit. __ __ (years)

B6. About how many cigarettes did you usually smoke per day before your breast cancer was diagnosed? __ __ (cigarettes)

B7. During periods when you smoked, did you smoke filter or non-filter cigarettes?

Filter .....1
Non-filter .....2
Both .....3

B8. When smoking cigarettes, did you usually not inhale at all, or usually inhale into the chest?

Not at all .....1
Chest .....2

B9. Did you drink any alcoholic beverages (beer, wine or liquor) at least once a month for 6 months or longer before your breast cancer was diagnosed?

No (GO TO B14) .....0
Yes .....1

B10. At what age did you start drinking alcoholic beverage? __ __ (age)

B11. Did you drink alcoholic beverages during six months before your breast cancer was diagnosed?

No .....0
Yes (GO TO B13) .....1

B12. How old were you when you stopped drinking?

__ __ (age)

B13. How many years did you drink before your breast cancer was diagnosed? Please exclude any years that you quit.

___(years)

B14. During the five years before your breast cancer was diagnosed, how often did you engage in physical activities (job or leisure) for 20 minutes or more a time, to the point where you were out of breath or worked up a sweat?

Never .....0
Once per month or less .....1
2 to 4 times per month .....2
1 to 2 times per week .....3
3 to 4 times per week .....4
More than 4 times per week .....5

B15. Did you ever use an electric blanket, electric mattress pad, or heated water bed on a regular basis before your breast cancer was diagnosed?

No (GO TO C1) .....0
Yes .....1

B16. How many total years had you used one before your breast cancer was diagnosed?

__ __ (years)

B17. During the years in which you did use an electric blanket, electric mattress pad, or heated water bed, for how many months per year did you usually use one?

__ __ (months)

B18. When you used the electric blanket, electric mattress pad, or heated water bed, did you leave it turned on most of the time while you slept, or did you use it only to warm the bed before you slept?

Warm only .....1
On most of the time .....2

## SECTION C: MENSTRUAL HISTORY

Now, I would like to ask some questions about your menstrual periods.

C1. How old were you when you had first menstrual period?

__ __ (age)
Never (GO TO D1).....00

C2. Did you still have your menstrual periods three months before your breast cancer was diagnosed?

No .....0
Yes (GO TO C5).....1

C3. What was the reason you did not have a menstrual period three months before your breast cancer was diagnosed?

Uterus removed .....1
Ovaries removed.....2
Both uterus and ovaries removed.....3
Natural menopause .....4
Radiation therapy .....5
Drug therapy .....6
Pregnancy (GO TO C5) .....7
Other (SPECIFY) .....8

_____

C4. At what age did you have your last menstrual period if your periods stopped before your breast cancer was diagnosed?

__ __ (age)

C5. How old were you when your periods became regular, that is, the time from the beginning of one period to the beginning of the next did not vary by more than ten days?

__ __ (age)
Irregular (GO TO C8).....00

C6. Before your breast cancer was diagnosed, what was the average number of days from the start of one period to the start of next, during times when you had NOT been on "the pill" or using an IUD?

__ __ (days)

C7. Before your breast cancer was diagnosed, how many days did your period usually last, during times when you had NOT been on "the pill" or using an IUD?

__ __ (days)

C8. Before your breast cancer was diagnosed, has there ever been a time since you started menstruating when you have had no periods for four consecutive months or longer? Please exclude pregnancy, nursing and use of birth control pills.

No .....0
Yes .....1

## SECTION D: REPRODUCTIVE HISTORY

Now, I would like to ask you some questions about your pregnancy history.

D1. Did you have a pregnancy before your breast cancer was diagnosed, regardless of whether the pregnancy was carried to term?

No (GO TO D5) .....0
Yes .....1

D2. What is the total number of pregnancies you had before your breast cancer was diagnosed, regardless of whether the pregnancy was carried to term? Please exclude the pregnancy when your breast cancer was diagnosed.

__ __ (pregnancies)
Uncertain .....99

D3. What was the outcome of your (1st/2nd/etc.) pregnancy? (ASK EACH PREGNANCY SEPARATELY)

| Outcome | Pregnancy | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| A miscarriage (<20 weeks gestation) | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| A stillbirth (>20 weeks gestation) | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| An induced abortion | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| A tubal or ectopic pregnancy | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| Multiple births (at least one born live) | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| A single, live birth | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 |

D4. What was your age at your (1st/2nd/etc.) pregnancy?

Pregnancy 1 .....__ __ (age)
Pregnancy 2 .....__ __ (age)
Pregnancy 3 .....__ __ (age)
Pregnancy 4 .....__ __ (age)
Pregnancy 5 .....__ __ (age)
Pregnancy 6 .....__ __ (age)
Pregnancy 7 .....__ __ (age)
Pregnancy 8 .....__ __ (age)

D5. Was there ever a period of 12 months or longer during which you had unprotected intercourse on a regular basis (>3 times per month) but did not become pregnant before your breast cancer was diagnosed ?

No .....0
Yes .....1

D6. Did you visit a doctor, clinic or hospital for an infertility test?

No ..... 0
Yes ..... 1

D7. What was found to be the cause or causes?

Nothing found ..... 0
Problem with ovaries ..... 1
Tube blocked ..... 2
Problem with uterus ..... 3
Problem with both uterus and ovaries ..... 4
Endometriosis ..... 5
Male factor ..... 6
Other (SPECIFY) ..... 7
_____

## SECTION E: CONTRACEPTIVE HISTORY

Next, I would like to know the birth control methods you have used and the length of time you used.

E1. I would like to read you a list of birth control methods. Please tell me if you or your partner had ever used any of them before your breast cancer was diagnosed.

None ..... 0
Birth control pills ..... 1
Condom, rubber alone ..... 2
Foam, alone ..... 3
Condom and foam together ..... 4
Jelly, cream, suppository alone ..... 5
Diaphragm with jelly or cream ..... 6
Diaphragm without jelly or cream ..... 7
Douche ..... 8
IUD, loop, coil ..... 9
Female sterilization (tubes tied) ..... 10
Male sterilization (vasectomy) ..... 11
Rhythm or safe method by temperature or mucous test ..... 12
~~Rhythm or safe method~~ ..... 13
Withdrawal/pulling out ..... 14
Shots (monthly, bimonthly) ..... 15
Other (SPECIFY) _____ ..... 16

E2. Please list the birth control methods you used for six months or more before your breast cancer was diagnosed, the approximate length of time used, and age at which you started and stopped using it. (EACH METHOD AND ITS CONTINUOUS TIME SPAN OF USE SHOULD BE A SEPARATE ENTRY—IF THE RESPONDENT HAS USED THE SAME METHOD AT TWO DIFFERENT POINTS IN HER LIFE, TWO SEPARATE ENTRIES SHOULD BE MADE)

| | Contraceptive method (USE CODE from E1) | How long had you used it? (years) | At what age did you begin using it? | At what age did you stop using it? |
|---|---|---|---|---|
| 1. | _____ | _____ | _____ | _____ |
| 2. | _____ | _____ | _____ | _____ |
| 3. | _____ | _____ | _____ | _____ |
| 4. | _____ | _____ | _____ | _____ |
| 5. | _____ | _____ | _____ | _____ |
| 6. | _____ | _____ | _____ | _____ |

IF BIRTH CONTROL PILLS REPORTED (FROM E1), ASK E3, OTHERWISE GO TO F0.

E3. You mentioned that you used the birth control pills. I would like to know if you used any of the following pills, dates started and stopped, and complications.(WRITE DOWN ADDITIONAL TIME SPANS IF THE RESPONDENT USE A BRAND AT MORE THAN ONE POINTS IN HER LIFE)

| Birth control pill | Did you use it? Yes | No | When did you start? (month, year) | When did you stop using it? (month, year) | Did you have any complications due to using it? |
|---|---|---|---|---|---|
| 1. Triphasil | 1 | 0 | __/__ __ | __/__ __ | _____ |
| 2. Ortho-Novum | 1 | 0 | __/__ __ | __/__ __ | _____ |
| 3. Lo-Ovral | 1 | 0 | __/__ __ | __/__ __ | _____ |
| 4. Demulen | 1 | 0 | __/__ __ | __/__ __ | _____ |
| 5. Tri-Levlen | 1 | 0 | __/__ __ | __/__ __ | _____ |
| 6. Other (specify) _____ | 1 | 0 | __/__ __ | __/__ __ | _____ |

E4. Did you use any birth control pills within 3 months before the diagnosis of your breast cancer?

No .....0
Yes .....1

## SECTION F: MEDICAL HISTORY

Next, I would like to get some information about your medical history including medical problems, medical examinations, and medical treatments.

F0. How did your breast cancer initially present?

A lesion palpated in a routine physical examination.....1
A lesion palpated in a self-examination.....2
A lesion found in a routine mammography .....3
Malignant changes incidentally found in a microscopic examination .....4
Nipple discharge .....5
Enlarged lymph node(s) .....6

F1. Did you ever have lumps or changes in your breasts that were <u>not</u> malignant before your breast cancer was diagnosed?

No (GO TO F9).....0
Yes.....1

F2. When was it first noticed? __ __/__ __ (month, year)

F3. How old were you when you first noticed them? __ __ (age)

F4. How old were you when they were first diagnosed by a doctor? __ __ (age)
No diagnosis by a doctor.....00

F5. What was the diagnosis? (SPECIFY) _____ __ __ (code)

F6. Did you have a breast biopsy or lumpectomy related to diagnosing or treating this problem?

No .....0
Yes .....1

F7. Did you have a mammogram in connection with diagnosing or treating this problem?

No .....0
Yes .....1

F8. Did you have a breast examination performed by a doctor on you for diagnosing this problem?

No .....0
Yes .....1

F9. How many mammograms did you have as a routine examination of your breasts during five years before your breast cancer was diagnosed?

__ __ (mammograms)
None .....00

F10. How many clinical breast examinations have been performed by a doctor on you as a routine check-up of your breasts during five years before your breast cancer was diagnosed?

__ __ (examinations)
None .....00

F11. How many self-examinations of the breasts did you usually have per year during five years before your breast cancer was diagnosed? __ __ (examinations)
None .....00

F12. Did you ever have surgery of any type on your breasts one year before your breast cancer was diagnosed?

No (GO TO F16) .....0
Yes .....1

F13. Was this surgery performed for

Increasing breast size .....1
Decreasing breast size .....2
Changing breast shape .....3
Removing one breast .....4
Removing both breasts .....5
Other (SPECIFY) _____.....6

F14. How old were you when this surgery was performed? __ __ (age)

F15. Were there any complications during or after the procedure, such as leaking?

No .....0
Yes .....1

F16. Were you ever diagnosed with a cancer <u>not</u> in the breasts before your breast cancer was diagnosed?

No (GO TO F19) .....0
Yes .....1

F17. What was the cancer? (SPECIFY) _____ __ __ (code)

F18. How old were you when your cancer was first diagnosed? __ __ (age)

F19. Were you ever treated with radium, cobalt or other radioactive isotope before your breast cancer was diagnosed?

No .....0
Yes .....1

F20. Did you ever have a surgery on your ovaries before your breast cancer was diagnosed?

No (GO TO F23) .....0
Yes .....1

F21. What was the surgery? (SPECIFY) _____ __ __ (code)

F22. What was the medical problem that caused this surgery? (SPECIFY) _____ __ __ (code)

F23. Before your breast cancer was diagnosed, did you ever use estrogen such as Premarin other than for birth control? These could include vaginal creams or suppositories, also injections or skin patches.

No (GO TO F26) .....0
Yes .....1
Uncertain (GO TO F26).....9

F24. We'd like to know some details about the use before your breast cancer was diagnosed, according to each of the following forms:

| | Did you use estrogen before that date in the form of...? | | | How many times a day? | How many days used per month? | At what age did you start? | At what age did you stop? |
|---|---|---|---|---|---|---|---|
| | Yes | No | N/A | | | | |
| 1. Pills | 1 | 0 | 3 | __ | __ __ | __ __ | __ __ |
| 2. Shots | 1 | 0 | 3 | __ | __ __ | __ __ | __ __ |
| 3. Creams | 1 | 0 | 3 | __ | __ __ | __ __ | __ __ |
| 4.Suppositories | 1 | 0 | 3 | __ | __ __ | __ __ | __ __ |

F25. Did you use estrogen within 3 months before the diagnosis of your breast cancer?

No .....0
Yes .....1

F26. Before your breast cancer was diagnosed, did you ever use progesterone such as Provera, Amen or Aygestin other than for birth control? Progesterone is sometimes used in conjunction with estrogen. These could include vaginal creams or suppositories, also injections or skin patches.

No (GO TO G1) .....0
Yes .....1
Uncertain (GO TO G1) .....9

F27. I would like to know some details about the use according to each of the following forms:

| | Did you use progesterone before that date? In the form of...? | | | How many times a day? | How many days used per month? | At what age did you start? | At what age did you stop? |
|---|---|---|---|---|---|---|---|
| | Yes | No | N/A | | | | |
| 1. Pills | 1 | 0 | 3 | __ | __ __ | __ __ | __ __ |
| 2. Shots | 1 | 0 | 3 | __ | __ __ | __ __ | __ __ |
| 3. Creams | 1 | 0 | 3 | __ | __ __ | __ __ | __ __ |
| 4.Suppositories | 1 | 0 | 3 | __ | __ __ | __ __ | __ __ |

F28. I would like to read a number of reasons women are given female hormones. Please tell me if a doctor ever gave you female hormones for any of the following reasons.

To reduce discomfort from a dry vagina .....1
~~For heavy or irregular or too frequent menstrual periods~~ .....2
To help become pregnant .....3
To test to see if you were pregnant .....4
To end a pregnancy .....5
To prevent a miscarriage .....6
For difficulty in nursing or to dry up breast milk .....7
To prevent bone thinning .....8
As a skin treatment .....9
Other (SPECIFY) _____ .....10

## SECTION G: FAMILY HISTORY

Now, I would like to ask the history of breast cancer among your family members.

G1. How many full sisters do you have, living and deceased?

__ __ (full sisters)
None .....00

G2. How many half sisters do you have on your father's side, living and deceased?

__ __ (full sisters)
None .....00

G3. How many half sisters do you have on your mother's side, living and deceased?

__ __ (full sisters)
None .....00

G4. How many daughters do you have, living and deceased?

__ __ (daughters)
None .....00

G5. Has anyone in your family, that is, your parents, brothers, and sisters, your children, ever been diagnosed as having cancer?

No (GO TO G7) .....0
Yes .....1

G6. I'd like to know some details about cancer in the family members:

| | 1st family member | 2nd family member | 3rd family member |
|---|---|---|---|
| 1. Who was diagnosed as having cancer, that is, what is their relationship to you? (INDICATE IF HALF SISTER OR BROTHER) | _____ Relation | _____ Relation | _____ Relation |
| 2. What type of cancer did (he/she) have? | _____ Type of cancer | _____ Type of cancer | _____ Type of cancer |
| 3. How old was your (FAMILY MEMBER) when (he/she) was diagnosed as having cancer? | _____ Age | _____ Age | _____ Age |
| 4. Did (he/she) die of cancer? | No .....0<br>Yes ....1 | No .....0<br>Yes ....1 | No .....0<br>Yes ....1 |

G7. Has any of your grandparents, grandchildren, uncles and aunts ever been diagnosed with cancer?

No (GO TO H1) .....0
Yes .....1

G8. I would like to know some details about cancer in these relatives:

| | 1st relative | 2nd relative | 3rd relative |
|---|---|---|---|
| 1. Who was diagnosed as having cancer, that is, what is their relationship to you? | _____ Relation | _____ Relation | _____ Relation |
| 2. What type of cancer did (he/she) have? | _____ Type of cancer | _____ Type of cancer | _____ Type of cancer |
| 3. How old was your (FAMILY MEMBER) when (he/she) was diagnosed as having cancer? | _____ Age | _____ Age | _____ Age |
| 4. Did (he/she) die of cancer? | No .....0<br>Yes ....1 | No .....0<br>Yes ....1 | No .....0<br>Yes ....1 |

## SECTION H: DIETARY INFORMATION

Next, I would like to ask you some questions about your dietary habits.

H1. About ~~how many times did you go on a diet to lose weight before your breast~~ cancer was diagnosed?

Never .....0
1 to 2 times. .....1
3 to 5 times .....2
6 to 8 times .....3
9 to 11 times .....4
12 or more times.....5

H2. During the year before your breast cancer was diagnosed, did you take any vitamins or minerals?

No (GO TO H3) .....0
Yes fairly regularly .....1
Yes, but not regularly.....2

| | IF YES, how frequently did you take _____(NAME OF EACH VITAMIN) fairly regularly? (None=0 1-3 weeks=1 4-6 weeks=2 1 per day =3 2 per day=4 3 or more per day=5) | For how many years? (Less than 1=0 1-2 years=1 3-5 years=2 6-9 years=3 10 or more=4 ) |
|---|---|---|
| **Multiple Vitamins** | | |
| Stress-tabs type | _____ (code for frequency) | _____ (code for years) |
| Therapeutic, Theragran type | _____ | _____ |
| One-a-day type | _____ | _____ |
| **Other Vitamins** | | |
| Vitamin A | _____ | _____ |
| Vitamin E | _____ | _____ |
| Calcium or Tums | _____ | _____ |
| Vitamin C | _____ | _____ |

H3. Before your breast cancer was diagnosed how many units per Vitamin E tablets did you take?

None.....0
100.....1
200.....2
400.....3
1000.....4
Don't know.....9

H4. Before your breast cancer was diagnosed how many milligrams per Vitamin C tablets did you take?

None.....0
100.....1
200.....2
400.....3
1000.....4
Don't know.....9

H5. Did you take pills containing any of the following nutrients before your breast cancer was diagnosed?

Iron .....0
Beta-carotene.....1
Zinc.....2
Selenium.....3
No, or don't know.....9

H6. Before your breast cancer was diagnosed, what kinds of the following fat did you usually use in cooking? (to fry, stir-fry or sauté) (MARK ONLY ONE OR TWO)

Lard, fatback, bacon fat.....0
Pam or no oil.....1
Crisco.....2
Stick margarine.....3
Butter.....4
Soft tub margarine.....5
Oil.....6
1/2 butter, 1/2 margarine.....7
Low calorie margarine.....8
Don't know, or don't cook.....9

H7. Before your breast cancer was diagnosed, what kinds of fat did you usually add to your vegetables, potatoes, etc.? (MARK ONLY ONE OR TWO)

Lard, fatback, bacon fat.....0
Low calorie margarine.....1
Stick margarine.....2
Soft tub margarine.....3
1/2 butter, 1/2 margarine.....4
Butter.....5
Whipped butter.....6
Crisco.....7
Don't add fat.....9

H8. Before your breast cancer was diagnosed, how often did you eat a low-fat or non-fat version of the following food?

| | Always low-fat | Sometimes low-fat | Rarely low-fat |
|---|---|---|---|
| Cheese | 0 | 1 | 2 |
| Ice-Cream/Yogurt | 0 | 1 | 2 |
| Salad Dressing | 0 | 1 | 2 |

H9. Did you often add salt to your food before your breast cancer was diagnosed?

Seldom/Never.....0
Sometimes.....1
Always.....2

H10. Did you often add pepper to your food before your breast cancer was diagnosed?

Seldom/Never.....0
Sometimes.....1
Always.....2

H11. Did you often eat the skin of chicken before your breast cancer was diagnosed?

Seldom/Never.....0
Sometimes.....1
Always.....2

H12. Did you often eat the fat on meat before your breast cancer was diagnosed?

Seldom/Never.....0
Sometimes.....1
Always.....2

H13. Before your breast cancer was diagnosed, how often did you eat the following foods from restaurants or carry-outs? Remember to think about all meals (breakfast, lunch, dinner or snacks).

| Restaurant Food | Never in past year | 1-4 times past year | 5-11 times past year | 1-3 times a month | once a week | 2-4 times a week | almost every day |
|---|---|---|---|---|---|---|---|
| Fried Chicken | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| Burgers | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| Pizza | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| Chinese food | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| Mexican food | 0 | 1 | 2 | 3 | 4 | 5 | 6 |
| Fried fish | 0 | 1 | 2 | 3 | 4 | 5 | 6 |

H14. During the past year before your breast cancer was diagnosed, how often did you eat the following foods and what was your usual serving amount size: small, medium or large. If _____is medium size (READ MEDIUM SERVING FOR EACH FOOD). REFER TO THE CHARTS ON THE FOLLOWING PAGES.

During the past year before your breast cancer was diagnosed, how often did you eat the following foods and what was your usual serving amount size: small, medium or large. If _____ is medium size (READ MEDIUM SERVING FOR EACH FOOD) REFER TO THE CHARTS ON THE FOLLOWING PAGES.

| | HOW OFTEN | | | | | | | | | HOW MUCH | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Type of Food** | Never or less than once per month | 1 per mon | 2-3 per mon | 1 per week | 2 per week | 3-4 per week | 5-6 per week | 1 per day | 2+ per day | **Medium Serving** | | your Serving Size | |
| **FRUITS & JUICES** | | | | | | | | | | | S | M | L |
| Apples, applesauce, pears | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium or ½ cup** | 9 | 10 | 11 |
| Bananas | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium** | 9 | 10 | 11 |
| Peaches, apricots (fresh or canned) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium or ½ cup** | 9 | 10 | 11 |
| Cantaloupe (in season) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1/4 medium** | 9 | 10 | 11 |
| Cantaloupe (rest of year) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1/4 medium** | 9 | 10 | 11 |
| Watermelon (in season) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 slice** | 9 | 10 | 11 |
| Strawberries (in season) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Oranges | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium** | 9 | 10 | 11 |
| Grapefruit | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ medium** | 9 | 10 | 11 |
| Orange or grapefruit juice | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **6 ounce glass** | 9 | 10 | 11 |

During the past year before your breast cancer was diagnosed, how often did you eat the following foods and what was your usual serving amount size: small, medium or large. If _____ is medium size (READ MEDIUM SERVING FOR EACH FOOD) REFER TO THE CHARTS ON THE FOLLOWING PAGES.

| | HOW OFTEN | | | | | | | | | HOW MUCH | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Type of Food** | Never or less than once per month | 1 per mon | 2-3 per mon | 1 per week | 2 per week | 3-4 per week | 5-6 per week | 1 per day | 2+ per day | **Medium Serving** | | your Serving Size | |
| **FRUITS & JUICES** | | | | | | | | | | | S | M | L |
| Fruit drink with added vitamin C, such as Hi-C | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **6 ounce glass** | 9 | 10 | 11 |
| Any other fruit, including berries, fruit cocktail, grapes | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| **BREAKFAST FOODS** | | | | | | | | | | | S | M | L |
| High fiber, bran or granola cereals, shredded wheat | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium bowl** | 9 | 10 | 11 |
| Highly fortified cereals, such as Total, Just Right or Product 19 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium bowl** | 9 | 10 | 11 |
| Other cold cereals, such as corn flakes, Rice Krispies | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium bowl** | 9 | 10 | 11 |
| Cooked cereal, or grits | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium bowl** | 9 | 10 | 11 |

During the past year before your breast cancer was diagnosed, how often did you eat the following foods and what was your usual serving amount size: small, medium or large. If _____ is medium size (READ MEDIUM SERVING FOR EACH FOOD) REFER TO THE CHARTS ON THE FOLLOWING PAGES.

| | HOW OFTEN | | | | | | | | | | HOW MUCH | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Type of Food** | Never or less than once per month | 1 per mon | 2-3 per mon | 1 per week | 2 per week | 3-4 per week | 5-6 per week | 1 per day | 2+ per day | **Medium Serving** | | your Serving Size | |
| **BREAKFAST FOODS** | | | | | | | | | | | S | M | L |
| Milk on cereal | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Sugar added to cereals | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 teaspoon** | 9 | 10 | 11 |
| Eggs | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 egg=sm 2 eggs=med** | 9 | 10 | 11 |
| Bacon | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 slices** | 9 | 10 | 11 |
| Sausage | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 patties or links** | 9 | 10 | 11 |
| **VEGETABLES** | | | | | | | | | | | | | |
| String or green beans | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Peas | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Chili with beans | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **3/4 cup** | 9 | 10 | 11 |
| Other beans such as baked beans, pintos, kidney, limas and lentils | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **3/4 cup** | 9 | 10 | 11 |

During the past year before your breast cancer was diagnosed, how often did you eat the following foods and what was your usual serving amount size: small, medium or large. If _____ is medium size (READ MEDIUM SERVING FOR EACH FOOD) REFER TO THE CHARTS ON THE FOLLOWING PAGES.

| | HOW OFTEN | | | | | | | | | | HOW MUCH | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Type of Food** | Never or less than once per month | 1 per mon | 2-3 per mon | 1 per week | 2 per week | 3-4 per week | 5-6 per week | 1 per day | 2+ per day | **Medium Serving** | | your Serving Size | |
| **VEGETABLES** | | | | | | | | | | | S | M | L |
| Corn | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Winter squash/baked squash | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Tomatoes, tomato juice | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium or 6 oz. glass** | 9 | 10 | 11 |
| Red chili sauce, taco sauce, salsa picante | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 tablespoon** | 9 | 10 | 11 |
| Broccoli | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Cauliflower or brussels sprouts | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Spinach (raw) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **3/4 cup** | 9 | 10 | 11 |
| Spinach (cooked) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Mustard, turnip, or collard greens | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |

During the past year before your breast cancer was diagnosed, how often did you eat the following foods and what was your usual serving amount size: small, medium or large. If _____ is medium size (READ MEDIUM SERVING FOR EACH FOOD) REFER TO THE CHARTS ON THE FOLLOWING PAGES.

| | HOW OFTEN | | | | | | | | | HOW MUCH | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Type of Food** | Never or less than once per month | 1 per mon | 2-3 per mon | 1 per week | 2 per week | 3-4 per week | 5-6 per week | 1 per day | 2+ per day | **Medium Serving** | | your Serving Size | |
| **VEGETABLES** | | | | | | | | | | | S | M | L |
| Cole slaw, cabbage, sauerkraut | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Carrots, or mixed vegetables containing carrots | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Green salad | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium bowl** | 9 | 10 | 11 |
| Regular salad dressing & mayonnaise, including on sandwiches etc. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 tablespoon** | 9 | 10 | 11 |
| French fries and fried potatoes | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **3/4 serving** | 9 | 10 | 11 |
| Sweet potatoes, yams | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Other potatoes, including boiled, baked, mashed & potato salad | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium or ½ cup** | 9 | 10 | 11 |
| Rice | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **3/4 cup** | 9 | 10 | 11 |

During the past year before your breast cancer was diagnosed, how often did you eat the following foods and what was your usual serving amount size: small, medium or large. If _____ is medium size (READ MEDIUM SERVING FOR EACH FOOD) REFER TO THE CHARTS ON THE FOLLOWING PAGES.

| | HOW OFTEN | | | | | | | | | HOW MUCH | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Type of Food** | Never or less than once per month | 1 per mon | 2-3 per mon | 1 per week | 2 per week | 3-4 per week | 5-6 per week | 1 per day | 2+ per day | **Medium Serving** | | your Serving Size | |
| **VEGETABLES** | | | | | | | | | | | S | M | L |
| Any cook vegetable, including onions, summer squash | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Butter, margarine or other fat added to vegetables etc. | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 pats** | 9 | 10 | 11 |
| **MEAT, FISH POULTRY, LUNCH ITEMS** | | | | | | | | | | | | | |
| Hamburgers, cheeseburgers, meatloaf, beef burritos, tacos | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium or 4 ounces.** | 9 | 10 | 11 |
| Beef, (steaks, roasts, etc. including sandwiches) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **4 ounces.** | 9 | 10 | 11 |
| Beef stew or pot pie with carrots or other vegetables | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 cup** | 9 | 10 | 11 |

During the past year before your breast cancer was diagnosed, how often did you eat the following foods and what was your usual serving amount size: small, medium or large. If _____ is medium size (READ MEDIUM SERVING FOR EACH FOOD) REFER TO THE CHARTS ON THE FOLLOWING PAGES.

| | HOW OFTEN | | | | | | | | | HOW MUCH | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Type of Food** | Never or less than once per month | 1 per mon | 2-3 per mon | 1 per week | 2 per week | 3-4 per week | 5-6 per week | 1 per day | 2+ per day | **Medium Serving** | | your Serving Size | |
| **MEAT, FISH, POULTRY, LUNCH ITEMS** | | | | | | | | | | | S | M | L |
| Liver, including chicken livers | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **4 ounces** | 9 | 10 | 11 |
| Pork, including chops, roasts | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 chops or 4 ounces** | 9 | 10 | 11 |
| Fried chicken | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 small or 1 large piece** | 9 | 10 | 11 |
| Chicken or turkey (roasted, stewed or broiled including sandwiches) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 small or 1 large piece** | 9 | 10 | 11 |
| Fried fish or fish sandwich | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **4 ounces or 1 sandwich** | 9 | 10 | 11 |
| Tuna, tuna salad, or casserole | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |

During the past year before your breast cancer was diagnosed, how often did you eat the following foods and what was your usual serving amount size: small, medium or large. If _____ is medium size (READ MEDIUM SERVING FOR EACH FOOD) REFER TO THE CHARTS ON THE FOLLOWING PAGES.

| | HOW OFTEN | | | | | | | | | HOW MUCH | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Type of Food** | Never or less than once per month | 1 per mon | 2-3 per mon | 1 per week | 2 per week | 3-4 per week | 5-6 per week | 1 per day | 2+ per day | **Medium Serving** | | your Serving Size | |
| **MEAT, FISH, POULTRY, LUNCH ITEMS** | | | | | | | | | | | S | M | L |
| Oysters | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **5 pieces, 1/4 cup or 3 oz.** | 9 | 10 | 11 |
| Shell fish, (shrimp, crab, lobster, etc) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **5 pieces, 1/4 cup or 3 oz.** | 9 | 10 | 11 |
| Other fish (broiled or baked) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 pieces or 4 ounces** | 9 | 10 | 11 |
| Spaghetti, lasagna, other pasta with tomato sauce | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 cup** | 9 | 10 | 11 |
| Pizza | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 slices** | 9 | 10 | 11 |
| Mixed dishes with cheese (such as macaroni & cheese) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 cup** | 9 | 10 | 11 |
| Liverwurst | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 slices** | 9 | 10 | 11 |
| Hot dogs | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 hot dogs** | 9 | 10 | 11 |

During the past year before your breast cancer was diagnosed, how often did you eat the following foods and what was your usual serving amount size: small, medium or large. If _____ is medium size (READ MEDIUM SERVING FOR EACH FOOD) REFER TO THE CHARTS ON THE FOLLOWING PAGES.

| | HOW OFTEN | | | | | | | | | HOW MUCH | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Type of Food** | Never or less than once per month | 1 per mon | 2-3 per mon | 1 per week | 2 per week | 3-4 per week | 5-6 per week | 1 per day | 2+ per day | **Medium Serving** | | your Serving Size | |
| **MEAT, FISH, POULTRY, LUNCH ITEMS** | | | | | | | | | | | S | M | L |
| Ham, bologna, salami & other lunch meats | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 slices or 2 ounces** | 9 | 10 | 11 |
| Vegetable and tomato soups including veg. beef, minestrone | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium bowl** | 9 | 10 | 11 |
| Other soups | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 med. bowl** | 9 | 10 | 11 |
| **BREADS, SNACKS, SPREADS** | | | | | | | | | | | | | |
| Biscuits, muffins, (including fast foods) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium piece** | 9 | 10 | 11 |
| White bread including sandwiches, bagels, burger rolls, french or italian bread | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 slices** | 9 | 10 | 11 |

During the past year before your breast cancer was diagnosed, how often did you eat the following foods and what was your usual serving amount size: small, medium or large. If _____ is medium size (READ MEDIUM SERVING FOR EACH FOOD) REFER TO THE CHARTS ON THE FOLLOWING PAGES.

| | HOW OFTEN | | | | | | | | | HOW MUCH | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Type of Food** | Never or less than once per month | 1 per mon | 2-3 per mon | 1 per week | 2 per week | 3-4 per week | 5-6 per week | 1 per day | 2+ per day | **Medium Serving** | | your Serving Size | |
| **BREADS, SNACKS, SPREADS** | | | | | | | | | | | S | M | L |
| Dark breads such as wheat, rye, pumpernickel (including sandwiches) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 Slices** | 9 | 10 | 11 |
| Corn bread, corn muffins, corn tortillas | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 medium pieces** | 9 | 10 | 11 |
| Salty snacks, such as potato chip, corn chip, popcorn | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 handfuls or 1 cup** | 9 | 10 | 11 |
| Peanuts, peanut butter | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 tablesps** | 9 | 10 | 11 |
| Margarine on bread/rolls | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 pats** | 9 | 10 | 11 |
| Butter on bread/rolls | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 pats** | 9 | 10 | 11 |
| Gravies made with meat drippings, or white sauce | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 tablesps** | 9 | 10 | 11 |

During the past year before your breast cancer was diagnosed, how often did you eat the following foods and what was your usual serving amount size: small, medium or large. If _____ is medium size (READ MEDIUM SERVING FOR EACH FOOD) REFER TO THE CHARTS ON THE FOLLOWING PAGES.

| | HOW OFTEN | | | | | | | | | HOW MUCH | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Type of Food** | Never or less than once per month | 1 per mon | 2-3 per mon | 1 per week | 2 per week | 3-4 per week | 5-6 per week | 1 per day | 2+ per day | **Medium Serving** | | your Serving Size | |
| **DAIRY PRODUCTS** | | | | | | | | | | | S | M | L |
| Cottage Cheese | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **½ cup** | 9 | 10 | 11 |
| Other cheeses & cheese spreads | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **2 slices or 2 ounces** | 9 | 10 | 11 |
| Flavored or frozen yogurt | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 cup** | 9 | 10 | 11 |
| **SWEETS** | | | | | | | | | | | | | |
| Ice-Cream | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 scoop or ½ cup** | 9 | 10 | 11 |
| Doughnuts, cookies, cake, pastry | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 piece or 3 cookies** | 9 | 10 | 11 |
| Pumpkin pie, sweet potato pie | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium slices** | 9 | 10 | 11 |
| Other pies | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 med. slice** | 9 | 10 | 11 |
| Chocolate candy | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 small bar or 1 oz** | 9 | 10 | 11 |

During the past year before your breast cancer was diagnosed, how often did you eat the following foods and what was your usual serving amount size: small, medium or large. If _____ is medium size (READ MEDIUM SERVING FOR EACH FOOD) REFER TO THE CHARTS ON THE FOLLOWING PAGES.

| | HOW OFTEN | | | | | | | | | HOW MUCH | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Type of Food** | Never or less than once per month | 1-3 per mon | 1 per week | 2-4 per week | 5-6 per week | 1 per day | 2-3 per day | 4-5 per day | 6+ per day | **Medium Serving** | | your Serving Size | |
| **SWEETS** | | | | | | | | | | | S | M | L |
| Other candy, jelly, honey, brown sugar | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **3 pieces or 1 tablespoon** | | | |
| **BEVERAGES** | | | | | | | | | | | | | |
| Whole milk & beverages with whole milk (not incl. on cereal) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **8 oz. glass** | 9 | 10 | 11 |
| 2% milk & beverage with 2% milk (not incl. on cereal) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **8 oz. glass** | 9 | 10 | 11 |
| Regular soft drinks (not diet soda) | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **12 oz. glass or bottle** | 9 | 10 | 11 |
| Beer | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **12 oz. glass or bottle** | 9 | 10 | 11 |
| Wine or wine coolers | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 medium glass** | 9 | 10 | 11 |
| Liquor | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | **1 shot** | 9 | 10 | 11 |

H15. I would like to ask you some summary questions about your dietary intake. How often did you use fat or oil in cooking in your foods within the year before your breast cancer was diagnosed?

Less than one per week.....1
1-2 per week.....2
3-4 per week.....3
5-6 per week.....4
1 per day.....5
11/2 per day .....6
2 per day.....7
3 per day.....8
4 or more per day.....9

H16. Within the year before your breast cancer was diagnosed, about how many servings of vegetables did you eat (not counting salad or potatoes)?

Less than one per week.....1
1-2 per week.....2
3-4 per week.....3
5-6 per week.....4
1 per day.....5
11/2 per day .....6
2 per day.....7
3 per day.....8
4 or more per day.....9

H17. Within the year before your breast cancer was diagnosed, about how many servings of fruits did you eat (not counting juices)?

Less than one per week.....1
1-2 per week.....2
3-4 per week.....3
5-6 per week.....4
1 per day.....5
11/2 per day .....6
2 per day.....7
3 per day.....8
4 or more per day.....9

H18. Within the year before your breast cancer was diagnosed how many servings of cold cereal did you eat?

Less than one per week.....1
1-2 per week.....2
3-4 per week.....3
5-6 per week.....4
1 per day.....5
11/2 per day .....6
2 per day.....7
3 per day.....8
4 or more per day.....9

## SECTION I: OTHER

Finally, I would like to ask you several additional questions. I would like to remind you that all information you give us is kept strictly confidential and you may refuse any of them. We appreciate your honesty in answering these questions.

I1. What was your religious preference when your breast cancer was diagnosed?

None .....0
Protestant .....1
Jewish .....2
Catholic .....3
Latter Day Saints .....4
Other (specify) _____.....5

I2. What was your household income before taxes in the year before your breast cancer was diagnosed?

Less than $15,000 .....1
$15,000 to $29,999 .....2
$30,000 to $44,999 .....3
$45,000 to $59,999 .....4
$60,000 or over ..... .....5

I3. How many people living in your household were supported by that income during that year?

__ __ (persons)

I4. How old were you when you first had sexual intercourse with a male?

__ __ (age)
Never (GO TO THE ENDING STATEMENTS) .....00
Uncertain .....99

I5. How old were you when you first had sexual intercourse on a regular basis?

__ __ (age)
Never .....00
Uncertain .....99

I6. On the average, how often did you have sexual intercourse with a male before age 20?

Never .....0
Less than once per month.....1
One to three times per month.....2
One to three times per week .....3
Four or more times per week .....4
Refused .....7
Uncertain .....9

I7. On the average, how often did you have sexual intercourse with a male between age 20 and 29?

Never .....0
Less than once per month .....1
One to three times per month.....2
One to three times per week .....3
Four or more times per week .....4
Refused .....7
Not available (younger than age 20) .....8
Uncertain .....9

I8. On the average, how often did you have sexual intercourse with a male between age 30 and 39?

Never .....0
Less than once per month .....1
One to three times per month.....2
One to three times per week .....3
Four or more times per week .....4
Refused .....7
Not available (younger than age 30) .....8
Uncertain .....9

I9. I would like to read a list of genital infections. Please let me know if you had any of them diagnosed by a doctor before your breast cancer was diagnosed. If you had one diagnosed, please tell me the age at which you first had it, and times you had it.

| | Were you diagnosed with it? Yes | No | Uk | At what age were you first diagnosed? | How many times did you have it? |
|---|---|---|---|---|---|
| 1. Venereal warts or condylomata | 1 | 0 | 3 | __ __ | __ __ |
| 2. Genital herpes | 1 | 0 | 3 | __ __ | __ __ |
| 3. Syphilis | 1 | 0 | 3 | __ __ | __ __ |
| 4. Gonorrhea | 1 | 0 | 3 | __ __ | __ __ |
| 5. Other sexually-transmitted diseases | 1 | 0 | 3 | __ __ | __ __ |

**I would like to thank you very much for your participating in this study. We appreciate you for your time and your help. As you know, we will be mailing you a check for $35.00. Please let me know if you have any questions about this study. this**

**IF RESPONDENT SAYS "YES", ANSWER THE QUESTION.**
**IF RESPONDENT SAYS "NO", SAY *"bye-bye".***

## SECTION J: INTERVIEWER REMARKS

J1. Respondent's overall cooperation was:

Very good.....1
Good.....2
Fair.....3
Poor.....4

J2. The quality of information obtained from this interview is

Very reliable .....1
Generally reliable .....2
Questionable .....3
Unsatisfactory .....4

J3. The main reason for unsatisfactory or questionable quality of this interview was that the respondent:

Was physically ill .....1
Had poor hearing or speech .....2
Did not understand or speak English well .....3
Was insufficiently knowledgeable .....4
Was confused or distracted by frequent interruptions .....5
Was inhibited by others around her .....6
Was bored or uninterested .....7
Was upset or depressed .....8
Was embarrassed by the subject matter .....9
Was emotional unstable .....10
Was hostile or uncooperative .....11
Other (SPECIFY) _____ .....12

J4. The interview was conducted with the respondent while she was

Alone .....1
With husband present .....2
With others present and listening (SPECIFY) .....3

# *Meharry Medical College Women's Health Study*

## *The Interviews' Overview*

*An interview is a structured procedure with a scientific purpose by means of which the respondent, through a series of questions is induced to give verbal information. The personal interview, whether face-to-face or by telephone, is the commonest method of collecting data on exposure in epidemiological studies..*

# *Four General Ways in Which the Performance of Interviews May Give Rise to Error*

- *Asking errors: Omitting questions or changing the wording of questions.*
- *Probing errors: Failing to probe when necessary, biased probing, irrelevant probing, inadequate probing.*

## *Four General Ways in Which the Performance of Interviews May Give Rise to Error (cont)*

- *Recording errors: Recording something not said, not recording something said, incorrectly recording what was said.*

- *Flagrant cheating: Recording a response when a question is not asked or answered.*

## *There are Two Types and Styles of Interviews*

- *Structured interview-Is one in which all the interview's tasks, and even words, are set down on the interview questionnaire.*

- *Unstructured interview-A rapport is established with the study subject.*

## *The Optimal Circumstances for an Interview Is Time and Place*

- *Time should be chosen to minimize, competing demands on the respondent.*
- *The easiest group to find at home at any time are those 65 years and older.*
- *Day of week is important in determining whether or not a respondent will be available.*

## *The Optimal Circumstances for an Interview Is Time and Place (cont)*

*Research has found that weekday evening, Saturday any time & Sunday afternoons and evenings to be the best time for an interview.*

## *Choosing the Location for the Interview*

- *The location of the interview should be chosen so that it is away from distractions.*

- *The interview should be able to sit facing the respondent, (so that the respondent cannot read the questionnaire), Ideally at a table so that it is easier for the interview to organize his or her papers.*

## *Securing the Interview*

- *The interviewer should establish her identity by showing an official ID card from the institution conducting the research.*

- *The interviewer should adopt a positive manners, assuming that the interview will not be refused.*

## *Questions Commonly Asked by the Respondent*

- *How did you happen to pick me?*
- *Who gave you my name/address?*
- *I really don't know anything about this.*
- *What's all this about anyway?*
- *What good will this do?*
- *What's the catch?*
- *What else am I going to have to do?*
- *Why do you need my name?*

## *Questions Commonly Asked by the Respondent (cont)*

- *How can I be sure that you won't tell everyone else what I tell you?*
- *Why do you want to know that?*
- *What are you going to do with these answers anyway?*
- *When will I get paid?*

## *Avoiding Refusals*

*If it appears that the respondent is going to refuse to be interviewed, the positive reasons for participation should be restated and any implied questions behind the refusal should be answered. As far as possible, a refusal should not be accepted until it is explicit.*

## *Asking Questions and Obtaining Answers*

- *Questions should be read with correct intonation and emphasis.*
- *Questions should be read slowly, about two words a second.*
- *When a respondent mishears or misunderstands a question, it should be repeated in full.*

## *Rules for Asking Questions in Highly Structured Interviews*

- *Read the questions exactly as they are worded in the questionnaire.*
- *Read each question slowly.*
- *Use correct intonation and emphasis*
- *Ask the questions in order they they are presented in the questionnaire.*
- *Ask every question that applies to the respondent .*

## *Rules for Asking Questions in Highly Structured Interviews (cont)*

- *Use response cards when provided.*
- *Repeat in full question that are misheard or misunderstood.*
- *Use only allowable probes.*
- *Read all linking or transitional statements exactly as they are printed.*
- *Do not add apologies or explanations for questions unless they are printed in the questionnaire.*

## *Acceptable Non-directive Probes*

- *Repeat the question.*
- *The expectant pause.*
- *Repeat the reply.*
- *Neutral questions or comments (for clarification).*

## *Rules for Recording Responses in Interviews*

- *Make sure that you understand each response.*
- *Make sure that each response is adequate.*
- *Do not answer for the respondent.*
- *Record all response during the interview*
- *Begin writing as soon as the respondent begins talking.*

GUIDELINES FOR TELEPHONE INTERVIEW

**Purposes of Improving Interview Skills**

1) To increase the response rate
2) To obtain accurate information
3) To obtain complete data and reduce missing items

**Issues For A Good Interview**

1) Psychological Preparations

- Perform an interview as if you have no knowledge of study group
- Perform an interview as if you have no knowledge of study aims
- Do not expect whether an interview will be difficult or not

2) Interview Time

- Tell a study subject time length for an interview to ensure sufficient time
- Convenient for study subjects
- Make an appointment if necessary

3) Speaking on the phone

- Friendly
- Nice

4) Introduction

- Read introduction remarks as presented in the questionnaire

5) Asking Questions

- Read a question as it is in the questionnaire
- In the order presented in the questionnaire
- Ask all questions needed (skip when indicated)

- Read all linking or transitional statements
- Read slowly and clearly
- Repeat a question, when necessary, in full
- Use non-directive probing
- No inductive questioning and directive probing
- Provide question-by-question feedback

7) Recording Answers

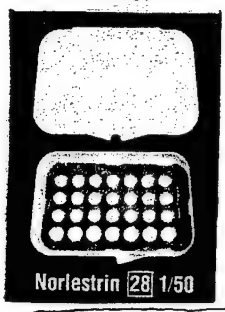
- Record only what has been said by study women
- Record it correctly
- Write a note when an answer is not clear

8) Editing

- Check all answers immediately after an interview (missing, unclear,…)
- Go back immediately to make up

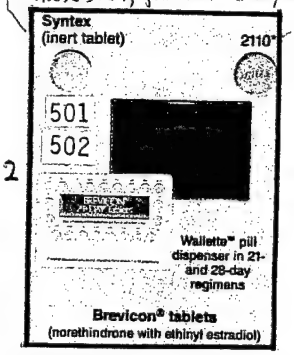
645

1



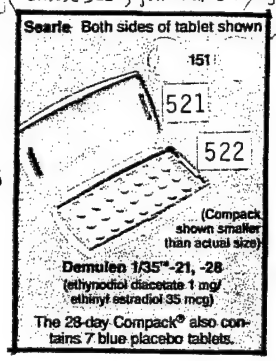

Choose 501 if you used 21-day regimen
Choose 502 if you used 28-day regimen

2



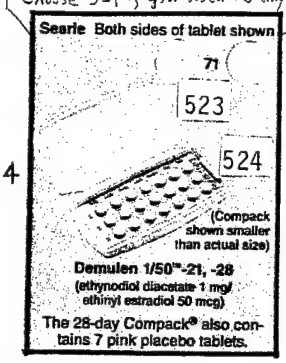

Choose 521 if you used 21-day regimen
Choose 522 if you used 28-day regimen

3



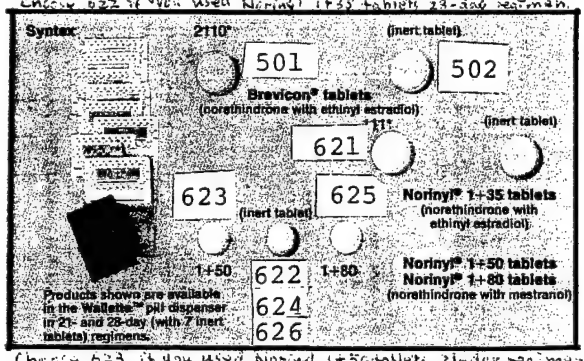

Choose 523 if you used 21-day regime
Choose 524 if you used 28-day regimen

4




Choose 501 if you used Brevicon tablets 21-day regimen.
Choose 502 if you used Brevicon tablets 28-day regimen.
Choose 621 if you used Norinyl 1+35 tablets 21-day regimen.
Choose 622 if you used Norinyl 1+35 tablets 28-day regimen.

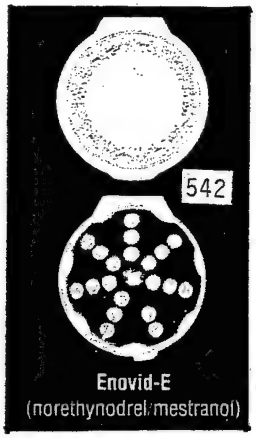
5



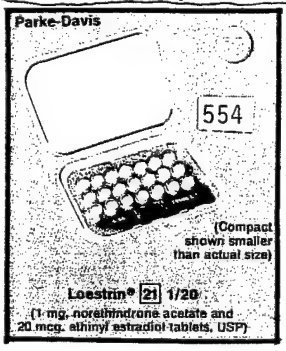

Choose 623 if you used Norinyl 1+50 tablets 21-day regimen
Choose 624 if you used Norinyl 1+50 tablets 28-day regimen
Choose 625 if you used Norinyl 1+80 tablets 21-day regimen
Choose 626 if you used Norinyl 1+80 tablets 28-day regimen

6

7



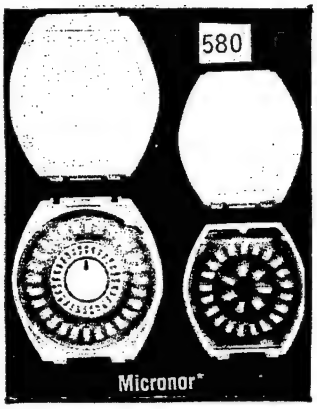

8




9

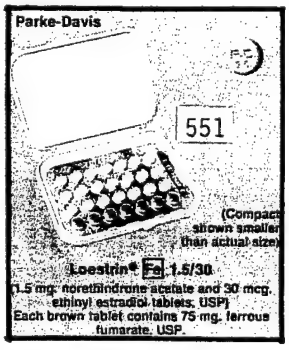
10

11

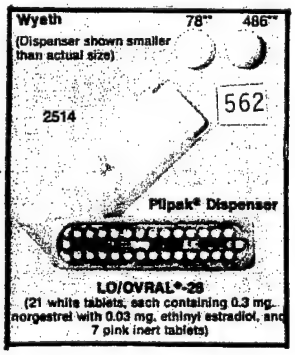



12

13



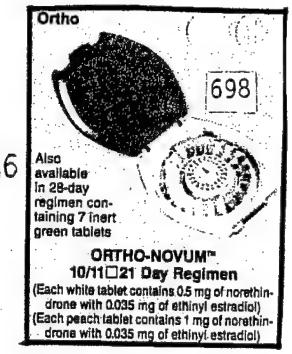

14



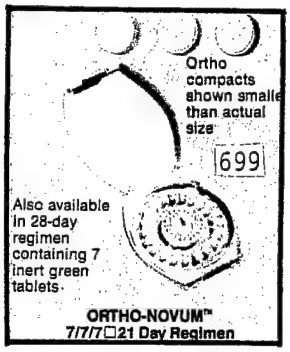

15

751

16



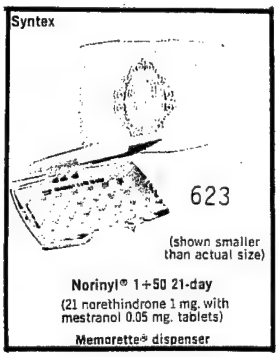

17



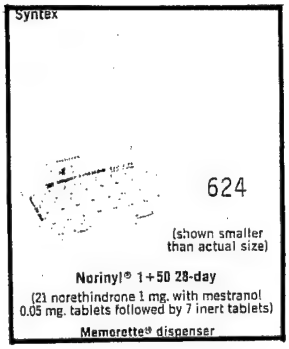

18

Choose 621 if you used 21-day regimen
Choose 622 if you used 28-day regimen

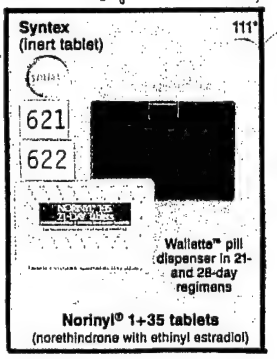
19



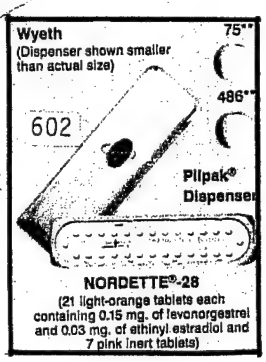

20




21

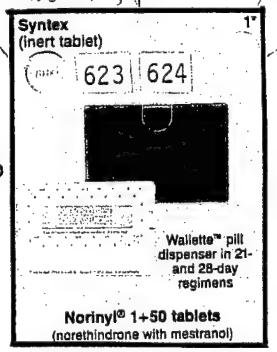



22

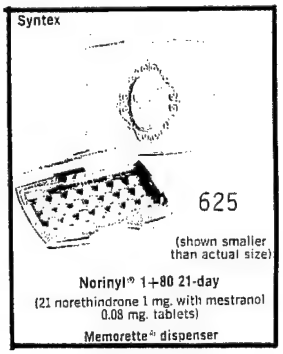



Choose 623 if you used 21-day regimen
Choose 624 if you used 28-day regimen

23



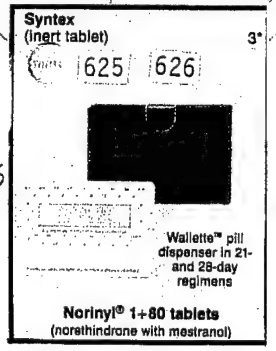

24



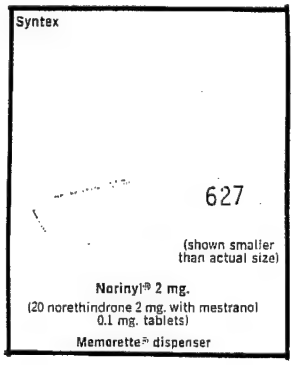

25

Choose 625 if you used 21-day regimen
Choose 626 if you used 28-day regimen

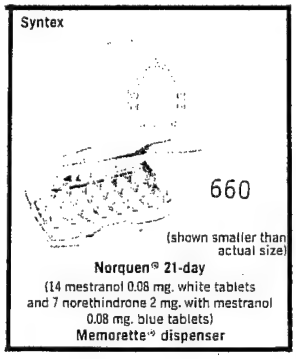
26



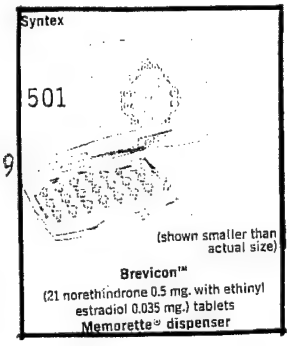

27




28

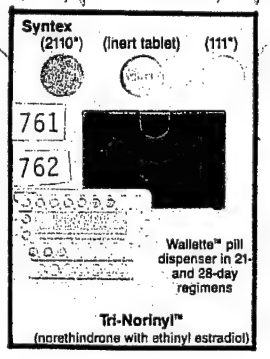



29




Choose 761 if you used 21-day regimen
Choose 762 if you used 28-day regimen

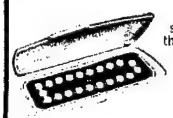
30



Choose 543 if you used 5-mg tablets
Choose 544 if you used 10-mg tablet

31

Parke-Davis



(Petipac® shown smaller than actual size)

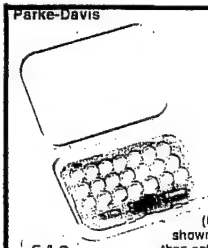
642

Norlestrin® 21 1/50

(1 mg norethindrone acetate and 50 mcg ethinyl estradiol tablets, USP)

32

Parke-Davis



642

(Compact shown smaller than actual size)

Norlestrin® 21 1/50

(1 mg. norethindrone acetate and 50 mcg. ethinyl estradiol tablets, USP)

Choose 681 if you used 21-day regimen
Choose 682 if you used 28-day regimen

33

Mead Johnson Laboratories

681 (ethinyl estradiol)

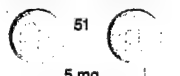
682 (ethinyl estradiol with dimethisterone)

Oracon® tablets

34

Searle

Both sides of tablets shown



51

5 mg (norethynodrel 5 mg/mestranol 75 mcg) 543

101

10 mg

Enovid® (norethynodrel 9.85 mg/mestranol 0.15 mg) 544

35

Parke-Davis

644

(Petipac® shown smaller than actual size)

Norlestrin® 21 2.5/50

(2.5 mg norethindrone acetate and 50 mcg ethinyl estradiol tablets, USP)

36

Parke-Davis

644

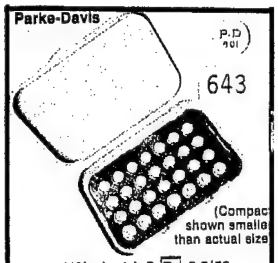
(Compact shown smaller than actual size)

Norlestrin® 21 2.5/50

(2.5 mg. norethindrone acetate and 50 mcg. ethinyl estradiol tablets, USP)

37

Parke-Davis



643

(Compact shown smaller than actual size)

**Norlestrin® Fe 2.5/50

(2.5 mg. norethindrone acetate and 50 mcg. ethinyl estradiol tablets, USP) Each brown tablet contains 75 mg. ferrous fumerate, USP.

38

Wyeth

641 642 643

(Compact shown smaller than actual size)

2535 781

TRIPHASIL®-21

(21 tablets containing the following: 6 brown tablets—0.050 mg. levonorgestrel + 0.030 mg. ethinyl estradiol; 5 white tablets—0.075 mg. levonorgestrel + 0.040 mg. ethinyl estradiol; 10 light-yellow tablets—0.125 mg. levonorgestrel + 0.030 mg. ethinyl estradiol)

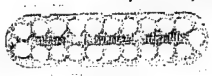
39

Wyeth

(Dispenser shown smaller than actual size)

731

Pilpak® Dispenser



OVRAL®

(0.5 mg. norgestrel with 0.05 mg. ethinyl estradiol)

40

Wyeth

(Dispenser shown smaller than actual size)

732

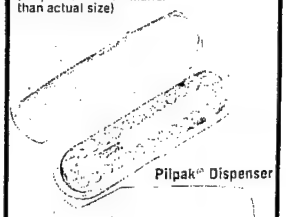
OVRAL®-28 Pilpak® Dispenser

(21 white tablets each containing 0.5 mg. norgestrel with 0.05 mg. ethinyl estradiol and 7 pink inert tablets)

41

Wyeth

(Dispenser shown smaller than actual size)



Pilpak® Dispenser

740 OVRETTE® (norgestrel)

42

Lederle

(Shown smaller than actual size)

771

Zorane™ 1/20

(norethindrone acetate 1 mg. and ethinyl estradiol 20 mcg.)

Pink Tablets

43

Lederle

(Shown smaller than actual size)

772

Zorane™ 1.5/30

(norethindrone acetate 1.5 mg. and ethinyl estradiol-30 mcg.)

Blue Tablets

44

Lederle

(Shown smaller than actual size)

Zorane™ 1/50 773

(norethindrone acetate 1 mg. and ethinyl estradiol 50 mcg.)

Green Tablets

45

Wyeth

641 642 643 650

(Compact shown smaller than actual size)

2536 782

TRIPHASIL®-28

(28 tablets containing the following: 6 brown tablets—0.050 mg. levonorgestrel + 0.030 mg. ethinyl estradiol; 5 white tablets—0.075 mg. levonorgestrel + 0.040 mg. ethinyl estradiol; 10 light-yellow tablets—0.125 mg. levonorgestrel + 0.030 mg. ethinyl estradiol; 7 light-green tablets—inert)

46 691 Ortho-Novum* 1/35 ⊡ 21

47 692 Ortho-Novum* 1/35 □ 28

48 693 Ortho-Novum* 1/50 □ 21

49 694 Ortho-Novum* 1/50 □ 28

50 695 Ortho-Novum* 1/80 □ 21

51 696 Ortho-Novum* 1/80 □ 28

52 641 Norlestrin Fe 1/50

53 697 Ortho-Novum* 2 mg □ 21

54 570 Modicon*

55 752 Ovulen-28

56 571 Modicon* 28

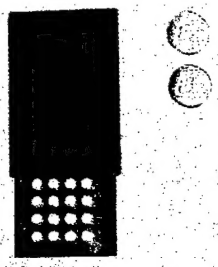
57 590 Nor-Q D

58 Ovcon-35 721

59 Ovcon-50 722

60

Berlex



†Levlen® 28 Tablets
28-Day Regimen
(Each light-orange tablet contains 0.15 mg levonorgestrel and 0.03 mg ethinyl estradiol. Each pink tablet is inert.)

794

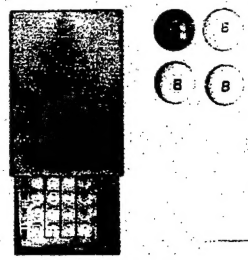
Also available in 21-day regimen

793

Choose 793 if you used 21-day regimen
Choose 794 if you used 28-day regimen

61

Berlex



†Tri-Levlen® 28 Tablets
28-Day Regimen
(Each brown tablet contains 0.050 mg levonorgestrel and 0.030 mg ethinyl estradiol. Each white tablet contains 0.075 mg levonorgestrel and 0.040 mg ethinyl estradiol. Each light-yellow tablet contains 0.125 mg levonorgestrel and 0.030 mg ethinyl estradiol. Each light-green tablet is inert.)

792

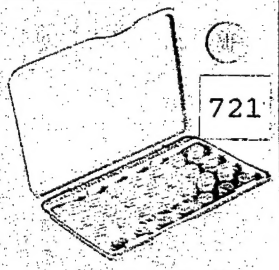
Also available in 21-day regimen

791

Choose 791, if you used 21-day regimen
Choose 792, if you used 28-day regimen

62

Mead Johnson Laboratories



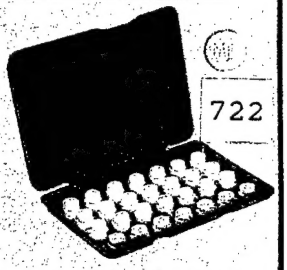
721

(Compact shown not actual size)

Ovcon®-35
(norethindrone and ethinyl estradiol)

63

Mead Johnson Laboratories



722

(Compact shown not actual size)

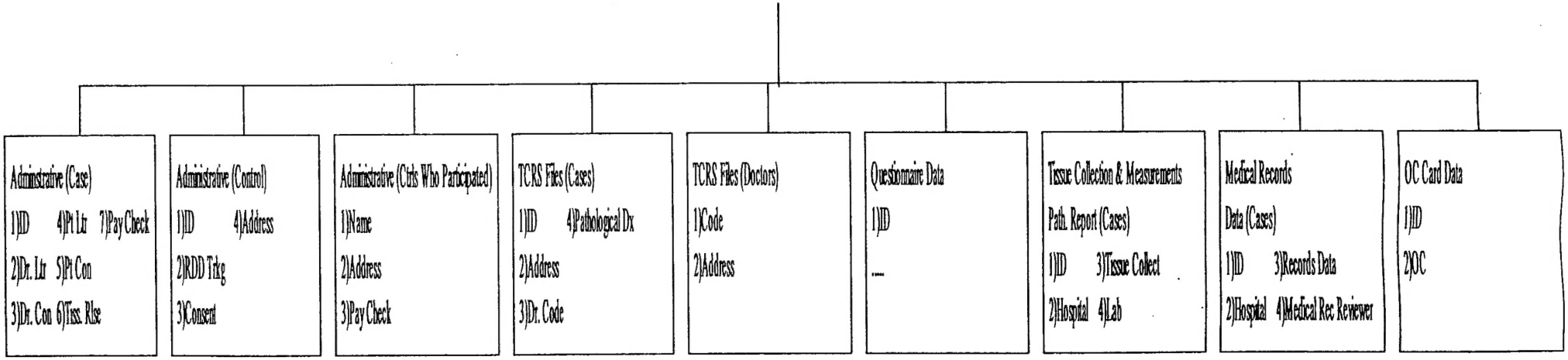
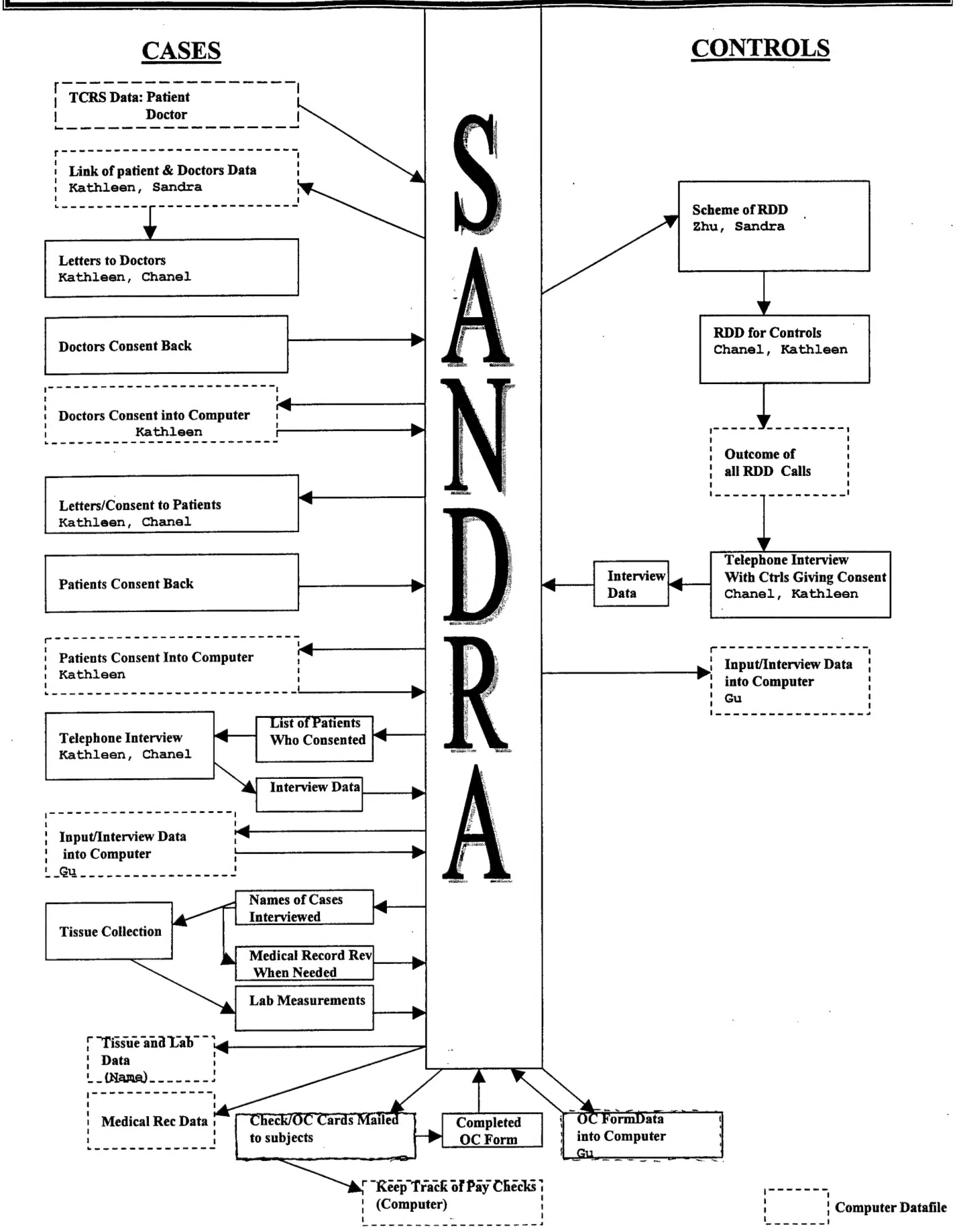
Ovcon®-50
(norethindrone and ethinyl estradiol)

On the enclosed color pictures, we show various brands of oral contraceptive pills. Please identify the pills you have ever used and put the picture number (in red color) and code number of each brand used in the space on the first column below. Also please write down the dates started and stopped, complications and the reasons for the use. If you have used a brand for more than one time-spans, please indicate each time span of use.

| Birth control pill (the picture number and code number) | When did you start? (month, year) | When did you stop using it? (month, year) | What was the reason to use this pill? | Did you have any complications due to using it? |
|---|---|---|---|---|
| 1. _____ _____ picture# code# | __/__ __ | __/__ __ | _____ | _____ |
| 2. _____ _____ picture# code# | __/__ __ | __/__ __ | _____ | _____ |
| 3. _____ _____ picture# code# | __/__ __ | __/__ __ | _____ | _____ |
| 4. _____ _____ picture# code# | __/__ __ | __/__ __ | _____ | _____ |
| 5. _____ _____ picture# code# | __/__ __ | __/__ __ | _____ | _____ |
| 6. _____ _____ picture# code# | __/__ __ | __/__ __ | _____ | _____ |
| 7. _____ _____ picture# code# | __/__ __ | __/__ __ | _____ | _____ |
| 8. _____ _____ picture# code# | __/__ __ | __/__ __ | _____ | _____ |
| 9. _____ _____ picture# code# | __/__ __ | __/__ __ | _____ | _____ |
| 10. _____ _____ picture# code# | __/__ __ | __/__ __ | _____ | _____ |

# Case-Control Study Tracking System

## (Linked through ID#)



# Data Handling
## (Case-Control Study)